DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 24, 2015

Integrated Healing Technologies
Mr. Ian Baird
Manager of Regulatory & Technology Affairs
103 Forrest Crossing Boulevard, Suite 103
Franklin, Tennessee 37064

Re: K142956
Trade/Device Name: NewEra Dome Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: January 9, 2015
Received: January 13, 2015

Dear Mr. Baird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142956

Device Name
NewEra Dome Kit

Indications for Use *(Describe)*
The NewEra Dome Kit is intended to be used with the NewEra I and II pumps. The system is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formations and perfusion, and by removing exudate and infectious material.
NPWT is appropriate for use on the following wounds:
- Pressure Ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Chronic, Acute, Traumatic, and Subacute wounds
- Post-operative and dehisced surgical wounds
- Explored fistulas
- Skin flaps and grafts

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Integrated Healing Technologies' NewEra Dome Kit

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Integrated Healing Technologies
103 Forrest Crossing Blvd.
Suite 103
Franklin, TN 37064

Phone: 615-468-2491
Facsimile: 615-472-8455

Contact Person: Ian Baird, Manager of Regulatory & Technology Affairs

Date Prepared: 10/10/2014

Name of Device

NewEra Dome Kit

Common or Usual Name

Negative Pressure Wound Therapy (NPWT) Kit

Classification Name

OMP - Negative pressure wound therapy powered suction pump (21 CFR 878.4780)

Predicate Devices

KCI NPWT Gauze Dressing Featuring SensaT.R.A.C. Technology (K123507);

RENASYS – G Gauze with RENASYS Soft Port (K110647)

Indications for Use

The NewEra Dome Kit is intended to be used with the NewEra I and II pumps. The system is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formations and perfusion, and by removing exudate and infectious material.

NPWT is appropriate for use on the following wounds:

- Pressure Ulcers
- Diabetic/neuropathic ulcers
- Venous insufficiency ulcers
- Chronic, Acute, Traumatic, and Subacute wounds
- Post-operative and dehisced surgical wounds

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- Explored fistulas
- Skin flaps and grafts

Device Description

The NewEra Dome Kit is a convenience kit offered in three sizes: small, medium, and large. The kit contains individually sterilized and packaged products, except PhaseOne which is not sterile. All products in the kit are 510(k) approved or exempt, except for the IHT NPWT dome (IHT dome). The kit includes an IHT dome to connect to a waste canister, PhaseOne Skin and Wound Cleanser, SkinTac, a ruler, one or more Cutimed Sorbact Compresses, and one or more transparent film IHT drapes (IHT drape), depending on the size. PhaseOne (K131542, K113820, K081009, K071056) and Cutimed Sorbact (K063059) are 510(k) approved devices. The IHT drape, SkinTac and ruler are Class I 510(k) exempt.

The PhaseOne is used to cleanse the wound. Cutimed Sorbact is then fluffed and filled into the wound. SkinTac is used on the border of the wound. The IHT Drape is applied to seal the wound. A hole is cut in the drape and the IHT NPWT dome is placed over the hole to allow suction. The NewEra Dome Kit attaches to an exudate canister to carry exudate from the wound and encourage wound closure.

The IHT dome and tubing are made of a medical grade thermoplastic elastomer, and the drapes and dome skirt are clear polyurethane films which are all common materials currently found in similar wound care products with established biocompatibility.

Technological Characteristics

The NewEra Dome Kit attaches to an exudate canister to carry exudate from the wound. The NewEra Dome Kit interacts with a NPWT pump that applies a negative pressure to the wound via the components of the kit. The dome has a unique, but similar design and is made of materials similar to its predicate devices.

Performance Data

Bench top performance and pressure testing was performed on the device to confirm the IHT Dome's ability to serve as a conduit between a NPWT Pump and NPWT dressing system for 72 hours. This testing confirmed that the IHT Dome and NewEra Dome kit delivered negative pressure for 72 hours, removed exudate for 72 hours, and contributed to no alarms. Further testing confirmed that the pressure delivered at the wound bed was the same as listed on the pump, that the pressure was delivered in the timely manner, and that the leak alarm occurred as expected when a leak was manually created in the dressing.
A usability study was performed to validate the usability requirements for the NewEra Dome Kit with individuals who represented actual potential users. The users were trained and then asked to apply the NewEra Dome Kit to a wound model. All participants successfully applied the NewEra Dome Kit to the wound model.

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Substantial Equivalence

The NewEra Dome Kit is substantially equivalent in design, materials, technology, function and intended use to the predicate devices named above. Verification and validation testing has been conducted to demonstrate that the device is safe and effective for the intended use. A reference table is provided below comparing the NewEra Dome Kit to the predicates.

Integrated Healing Technologies' NewEra Dome Kit

SUBSTANTIAL EQUIVALENCE CHART

Element of Comparison	**New Era Dome Kit**	**Predicate KCI NPWT Gauze Dressing (K123507)**	**Predicate Renasys Gauze NPWT Dressing Kit (K110647)**
Manufacturer:	Integrated Healing Technologies, LLC.	KCI	Smith & Nephew
Product Type:	Negative Pressure Wound Therapy System	Negative Pressure Wound Therapy System (Gauze Component)	Power Suction Pump & Accessories
Product Code:	OMP	OMP, FRO	OMP
Indications for Use:	The NewEra Dome Kit is intended to be used with the NewEra pumps (k082311). The system is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formations and perfusion, and by removing exudate and infectious material. NPWT is appropriate for use on the following wounds: • Pressure Ulcers • Diabetic/neuropathic ulcers • Venous insufficiency ulcers	The *KCI NPWT Gauze Dressing* is intended to be used with the following KCI Therapy Units (ActiV.A.C., InfoV.A.C., V.A.C. Simplicity, V.A.C. Freedom, V.A.C. ATS and V.A.C. Ulta Therapy Systems). The system is intended to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infection material. Wound types include chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness	The RENASYS h Foam and Gauze Wound Dressing Kits with Softport are intended to be used in conjunction with Smith & Nephew NPWT systems. Smith & Nephew NPWT systems are indicated for patients who would benefit from a suction device (negative pressure wound therapy) as it may promote wound healing via the removal of fluids, including irrigation and body fluids, wound exudates and infectious materials. Examples of appropriate wound types include: chronic, acute, traumatic, sub-acute and dehisced wounds, ulcers (such as pressure or diabetic), partial-

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Element of Comparison	New Era Dome Kit	Predicate KCI NPWT Gauze Dressing (K123507)	Predicate Renasys Gauze NPWT Dressing Kit (K110647)
	• Chronic, Acute, Traumatic, and Subacute wounds • Post-operative and dehisced surgical wounds • Explored fistulas • Skin flaps and grafts	burns, ulcers (such as diabetic, pressure or venous insufficiency), flaps and grafts. The KCI NPWT Gauze Dressing is not intended for use with instillation therapy, intermittent therapy or over closed incisions.	thickness burns, flaps and grafts.
User Population:	Acute, extended, and home care	Acute, extended, and home care	Acute, extended, and home care
Dressing: • Material • Configuration	Dialkyl Carbamoyl Chloride on an acetate mesh 7 x 9 in. sheets, multiple size sheets available for small, medium and large wounds	Antimicrobial gauze (Polyhexamethylene Biguanide 0.2%) Identical to the large size of Renasys Gauze NPWT Dressing kit	Antimicrobial gauze (Polyhexamethylene Biguanide 0.2%) Multiple sizes available in roll and pad for small, medium and large wounds
Drape	Same as predicates	Polyurethane film with adhesive	Polyurethane film with adhesive
Interface pad and tubing	IHT Dome	V.A.C. SensaT.R.A.C. Pad	Softport assembly
Wound measuring ruler	Same as predicates	Provided	Provided
Accessories: Wound cleanser, skin prep	Provided	Not provided	Provided
NPWT Therapy Units Compatibility	Compatible with the NewEra I & II pumps (k082311)	Compatible with the following KCI V.A.C. Negative Pressure Wound Therapy Units: ActiV.A.C. InfoV.A.C. V.A.C. ATS V.A.C. Freedom V.A.C. Simplicity V.A.C. Ulta	Compatible with S&N therapy units: RENASYS EZ RENASYS GO
Single-use or Reusable:	Single-use	Single-use	Single-use
Method of Sterilization:	Individual kit components individually sterilized by Gamma Irradiation, except	Unknown	Individual kit components individually sterilized by Ethylene

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Element of Comparison	New Era Dome Kit	Predicate KCI NPWT Gauze Dressing (K123507)	Predicate Renasys Gauze NPWT Dressing Kit (K110647)
	the PhaseOne which is not sterile		Oxide or Gamma Irradiation
Packaging:	Pre-packaged, sterilized and placed in package as a convenience kit	Unknown	Pre-packaged, sterilized and placed in package as a convenience kit
Biocompatibility:	Meets ISO 10993	Unknown	Meets ISO 10993
Summary of non-clinical tests conducted for determination of substantial equivalence	The NewEra Dome Kit was evaluated under a number of design verification and validation tests to assure performance requirements for delivery of negative pressure wound therapy were met. • The NewEra Dome Kit, when used with the NewEra I or II pump, delivers negative pressure, as specified, to the wound for a period of 72 hours. • The NewEra Dome Kit, when used with the NewEra I or II pump, removes exudate from the wound for a period of 72 hours. • The NewEra Dome Kit, when used with the NewEra I or II pump, does not contribute to alarms. • Was applied successfully by users in a usability study.		
Summary of clinical tests conducted for determination of substantial equivalence	None required for determining substantial equivalence.		
Conclusions Drawn	Testing demonstrates that the NewEra Dome Kit, KCI NPWT Gauze dressing, and Renasys Gauze NPWT Dressing Kit with Softport are substantially equivalent in terms of both indications for use and delivery of negative pressure wound therapy.		